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| EXAMINER | |
|---|---|
| HINES, JANA A | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/761,237 | WENDEL ET AL. | |
| | Examiner | Art Unit | |
| | Ja-Na Hines | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *19-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Amendment Entry*

1. The amendment filed March 12, 2007 has been entered. The examiner acknowledges the amendments to the specification. Claims 1-18 have been cancelled. Claims 19-22 are under consideration in this office action.

### *Specification*

2. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading.

(Content of Specification)

(a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.

(b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.

(c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.

(d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).

(e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of

electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.

(f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:

(1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."

(2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

(g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

(h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

(i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention

described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.

(j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

(k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

### *Claim Objections*

3. Claims 19-22 refer to "In a method...", however the suggested claim language is to use of the article "A" or The." Therefore the suggested claim language is "A method of testing..." or "The method of testing...."

### *Withdrawal of Rejections*

4. The following rejections have been withdrawn in view of applicants' arguments:

a) The rejection of claims 19-21 under 35 U.S.C. 102(b) as being anticipated by Vora (US Patent 4,774,088).

### *Response to Arguments*

4. Applicant's arguments filed March 12, 2007 have been fully considered but they are not persuasive.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. The rejection of claims 19-22 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained.

Applicants argue that since the PTO understands the meaning of "standardized blood unit dose" well enough to find it in the cited prior art, therefore the claim term should not be considered indefinite, under § 112, ¶2. It is noted that the prior art did not explicitly recite "standardized blood unit dose" rather the art taught whole blood samples from a plurality of identical cryopreserved units from one lot of a whole blood sample, which meet the limitation of being in the form of a standardized blood unit dose. Furthermore, finding art is not the criteria upon which the indefiniteness is based. The standard is that claims must particularly point out and distinctly claim the subject matter which applicant regards as his invention. The phrase "standardized blood unit dose" in claims is a relative phrase which renders the claim indefinite. The phrase is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. There is no teaching of how the standardization occurs or by

whom the standardization is determined. Applicants' states that standardization depends on a variety of test, and multiple comparisons made at different times; and standard values are determined in advance under standardized condition based on abnormal blood reactions recognized in appropriate preliminary test. Therefore applicants' definition shows the indefiniteness concerning the meaning of standardized blood unit dose.

Thus, the metes and bounds of the phrase are unclear and the rejection is maintained.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Rubinstein et al., (PNAS, 1995. Vol. 92, pages 10119-10122).

Claim 19 is drawn to a method of testing a material or object for human applications by detecting and/or measuring an immunofunctional, toxic, or modulatory blood reaction against the material or object, the method comprising the steps of(i) contacting said material or object with a blood sample from a human or animal and (ii) detecting and/or measuring the immunofunctional, toxic, or modulatory blood reaction by a biological, physical, chemical, or physicochemical method, wherein the

improvement comprises using as the blood sample a thawed cryopreserved unit of whole blood, said cryopreserved unit (a) being selected from the group consisting of a plurality of identical cryopreserved units from one lot of a whole blood sample, (b) being in the form of a standardized blood unit dose, and (c) containing a cryopreservative.

Claim 20 is drawn to a method of testing a material or object for human applications by detecting and/or measuring an immunofunctional, toxic, or modulatory blood reaction against the material or object, wherein the improvement comprises using as the blood sample a thawed cryopreserved unit of whole blood, said cryopreserved unit contains a cryopreservative, the blood further comprising clotting inhibitors and/or diluents.

Claim 21 is drawn to a method of testing a material or object for human applications by detecting and/or measuring an immunofunctional, toxic, or modulatory blood reaction against the material or object, wherein the improvement comprises using as the blood sample a thawed cryopreserved unit of whole blood, said cryopreserved unit contains a cryopreservative and further comprising clotting inhibitors.

Claim 22 is drawn to a method of testing a material or object for human applications by detecting and/or measuring an immunofunctional, toxic, or modulatory blood reaction against the material or object, wherein the improvement comprises using as the blood sample a thawed cryopreserved unit of whole blood, said cryopreserved unit contains a cryopreservative and the blood sample further comprising diluents.

Rubinstein et al., teach a method of testing a material or object for human applications by detecting and/or measuring a modulatory blood reaction against a

material, the method comprising (i) contacting human albumin, dextran and an isotonic salt solution with placental cord whole blood sample from a human or animal (page 10, 120, col.2). Human albumin, dextran and an isotonic salt solution are materials contacted with the whole blood. Rubinstein et al., teach (ii) detecting and/or measuring viability measurements after contact with a material as a modulatory blood reaction by a physical cell counting method. Rubinstein et al., teach the improvement by using as the whole blood from a thawed cryopreserved unit of whole blood, wherein the whole blood unit bag is thawed for experimental work (page 10,120, col.2). Rubinstein et al., teach (a) blood samples from a plurality of identical cryopreserved units from one lot of a whole blood sample, and (b) being in the form of a standardized blood unit dose wherein the whole blood is from a standard blood transfusion bag (page 10,120, col.2). The standardized blood bags provide a plurality of identical units in the form of a standardized blood unit dose from one lot of whole blood sample. Rubenstein et al., teach the bags (c) containing a dimethyl sulfoxide (DMSO) cryopreservative was added to the blood bag and mixed with the diluent isotonic saline (page 10,120, col.2). The blood bag also contained the anticoagulant or clotting inhibitor citrate/phosphate/dextrose/adenine (page 10,120, col.1).

Therefore, Rubinstein et al., anticipate claims 19-22 of the instant application.

***Response to Arguments***

7. Applicant's arguments filed March 12, 2007 have been fully considered but they are not persuasive.

The rejection of claims 19-22 under 35 U.S.C. 102(b) as being anticipated by Rubinstein et al., (PNAS, 1995. Vol. 92, pages 10119-10122) is maintained.

Applicants' argue that Rubinstein, does not use whole blood an express limitation of the presently claimed invention. However, Rubinstein et al., teach Cryopreservation and Thawing Units After Storage in LN (Liquid Nitrogen) in the materials and method section. Here Rubinstein expressly states thawing crypreserved units of whole blood for experimental work. Therefore, contrary to applicants' statements Rubinstein et al., clearly teach the cyropreservation of whole blood.

Applicants argue that the bulk-reduced (non-whole) blood disclosed in Rubinstein is not suitable in the presently claimed testing method. However, contrary to applicants' statements, Rubinstein et al., teach each and every limitation of the instants claims. The fact that Rubinstein et al., separately teach the reduction of placental cord whole blood sample is irrelevant, because Rubinstein teach the testing of a material by contacting the material with a blood sample wherein the sample is a thawed cryopreserved unit of whole blood containing a cryopreservative, diluent and clotting inhibitors.

The MPEP section 2123 teaches that prior art is relevant for it contains and the use of references is not limited to what the author describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain. *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments.

*Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir.1998).

Rubinstein et al., clearly teach a contacting materials such as human albumin, dextran and an isotonic salt solution with placental cord whole blood sample from a human or animal (page 10, 120, col.2). Rubinstein et al., teach (ii) detecting and/or measuring viability measurements after contact with a material as a modulatory blood reaction by a physical cell counting method, see Tables 2 and 3. There are no limitations on the types of materials contacted with the blood or on the type of testing performed on the blood. There is not a even a requirement that the detecting correlate to the effect of contact of the material or object on the blood. Furthermore, applicants concede that testing a material or object for human applications by detecting and/or measuring an immunofunctional, toxic, or modulatory blood reaction against the material or object, is already well known in the art, in view of the claims Jepson format. Therefore applicant's argument that contacting the blood with a material and testing the blood thereafter is not persuasive especially when considering that Rubinstein et al., anticipate claims 19-22 of the instant application.

***Claim Rejections - 35 USC § 102***

8. Claims 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaye et al., (J. of Virological Methods, 1991. Vol. 35,pages 217-226).

Claim 19 is drawn to a method of testing a material or object for human applications by detecting and/or measuring an immunofunctional, toxic, or modulatory blood reaction against the material or object, the method comprising the steps of(i) contacting said material or object with a blood sample from a human or animal and (ii) detecting and/or measuring the immunofunctional, toxic, or modulatory blood reaction by a biological, physical, chemical, or physicochemical method, wherein the improvement comprises using as the blood sample a thawed cryopreserved unit of whole blood, said cryopreserved unit (a) being selected from the group consisting of a plurality of identical cryopreserved units from one lot of a whole blood sample, (b) being in the form of a standardized blood unit dose, and (c) containing a cryopreservative.

Claim 20 is drawn to a method of testing a material or object for human applications by detecting and/or measuring an immunofunctional, toxic, or modulatory blood reaction against the material or object, wherein the improvement comprises using as the blood sample a thawed cryopreserved unit of whole blood, said cryopreserved unit contains a cryopreservative, the blood further comprising clotting inhibitors and/or diluents.

Claim 21 is drawn to a method of testing a material or object for human applications by detecting and/or measuring an immunofunctional, toxic, or modulatory blood reaction against the material or object, wherein the improvement comprises using as the blood sample a thawed cryopreserved unit of whole blood, said cryopreserved unit contains a cryopreservative and further comprising clotting inhibitors.

Claim 22 is drawn to a method of testing a material or object for human applications by detecting and/or measuring an immunofunctional, toxic, or modulatory blood reaction against the material or object, wherein the improvement comprises using as the blood sample a thawed cryopreserved unit of whole blood, said cryopreserved unit contains a cryopreservative and the blood sample further comprising diluents.

Kaye et al., teach a method of testing a material or object for human applications by detecting a immunofunctional reaction against a material, the method comprising by a physicochemical PCR method (abstract). Kaye et al., teach the method of detection comprising (i) contacting Glycigel with a blood sample from a human (page 219, para.3). Kaye et al., teach a method of testing by (ii) detecting the immunofunctional, toxic, or modulatory blood reaction by a biological, physical, chemical, or physicochemical method (page 219, See sections entitled DNA extraction from Glycigel preserved samples and PCR). It is noted that in view of the broad interpretation of immunofunctional, toxic, or modulatory blood reaction by any biological, physical, chemical or physiochemical method, the performance of PCR which detects the presence of HIV meets the instantly recited limitation. There is no limitation of the type of resulting detection or measurement of the blood sample other than determining a blood reaction. Thus, the broad testing steps of the claims embrace both the extraction step and PCR performance, since there are no limitations on further manipulations of the whole blood sample. Kaye et al., teach the storage, preservation and thawing of patient whole blood samples, thereby having a thawed cryopreserved unit of whole blood (page 218, para. 5). Kaye et al., teach the cryopreserved unit being selected from

the group consisting of a plurality of identical cryopreserved units from one lot of a whole blood sample, in the form of a standardized blood unit wherein the samples were stored and transported to a central laboratory where they were batch processed (page 218, para. 2). Thus, a standardized blood unit dose is taught. Kaye et al., teach that several units of the donor blood were subjected to identical Glycigel cryopreservative treatment thereby teaching a standardized blood unit containing a cryopreservative (page 218-219, para. 5-2). Kaye et al., step (c) where whole blood samples comprising a glycerol/gelatin cryopreservative medium commonly known as Glycigel (page 218, para.2). Kaye et al., teach heparinised blood was taken from human donors whereby the blood was mixed with Glycigel, a commonly known cyropreservative, sodium azide and stored frozen (page 218, para. 4). Heparin is a clotting inhibitor, while sodium azide is a diluent.

Therefore, Kaye et al., anticipate claims 19-22 of the instant application.

***Response to Arguments***

9. The rejection of claims 19-21 under 35 U.S.C. 102(b) as being anticipated by Kaye et al., (J. of Virological Methods, 1991. Vol. 35,pages 217-226) is maintained.

Applicants argue that Kaye et al., do not teach a method for using whole blood for detecting and/or measuring an immunofunctional, toxic, or modulatory blood reaction against a material or object, as there is according to the presently claimed invention. However, contrary to applicants' statements, the cryopreservative, Glycigel is contacted with whole blood. DNA is extracted from the whole blood sample; however there is no

limitation in the claims that preclude extraction and PCR as a means for detecting and/or measuring an immunofunctional, toxic, or modulatory blood reaction against the material. The extraction does not change the fact that thawed cryopreserved whole blood samples were contacted with a material. The limitations of the claims are meet because an immunofunctional, toxic, or modulatory blood reaction against the material is measured or detected. Accordingly, the broad interpretation of immunofunctional, toxic, or modulatory blood reaction by any biological, physical, chemical or physiochemical method, the performance of PCR meets the instantly recited limitations. There are no limitations on the types of materials contacted with the blood or on the type of testing performed on the blood. There is not a even a requirement that the detection correlate to the contact of the material or object on the blood. Therefore applicant's argument that contacting the blood with a material and testing the blood thereafter is not persuasive especially when considering the breadth of the claims and the lack of limitations concerning the contact step and detection step; therefore Kaye et al., anticipate claims 19-22.

Furthermore, Jepson format is taken as an implied admission that the subject mater of the preamble is the prior art work of another. *In re Fout*, 675 F.2d 297, 301, 213 USPQ 532, 534 (CCPA 1982) (holding preamble of Jepson-type claim to be admitted prior art). Therefore, detecting and/or measuring an immunofunctional, toxic, or modulatory blood reaction against the material is admitted prior art. Therefore each and every limitation of the claims are taught. Thus, applicant's arguments are not

persuasive especially when considering that Kaye et al., anticipate claims 19-21 of the instant application.

***Conclusion***

10. No claims allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Jeffery Siew, can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
May 17, 2007

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER